Mammography Fact Sheet

for facilities within the State of California

In California, screening/diagnostic mammography is controlled by State law, through the California Health and Safety Code, Mammography Quality Assurance Act of 1992; State regulations, through the California Code of Regulations (CCR), Title 17, Article 4.5, effective July, 2003; Federal law, through the Mammography Quality Standards Act (MQSA) of 1992, amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998; and by Federal regulations, through 21 Code of Federal Regulations (CFR), Part 900, effective April, 1999. All mammography facilities must satisfy the requirements of *all* of these laws and regulations. Federal laws and regulations *do not* negate State laws and regulations. Federal requirements *are in addition to* State requirements. Mammography can be performed legally in California only after a facility has received and posted a facility certificate (or interim notice) issued directly from the Federal Food and Drug Administration (FDA) *and* individual certificate(s) issued by the California Department of Health Services (DHS) to each machine used for mammography.

> No patient examinations may be performed until you have the appropriate authorization and *all* certificates have been received. This means that an applications specialist may not conduct training on a new machine if human breast images will be taken until you have current FDA certification *and* a new state certificate for that specific machine. As a result, please be aware that you must make the appropriate agency notifications *in advance* in order to fulfill the necessary requirements to receive your certificates and begin performing mammography.

FDA Certification is facility-based and results in one certificate issued for each facility. The FDA must certify your facility before you perform screening/diagnostic mammography. For your facility to be certified by the FDA, an accrediting body (AB) approved by the FDA must accredit your facility. The only AB approved by the FDA for mammography facilities in California is the American College of Radiology (ACR) - (800) 227-6440. After you have completed accreditation requirements, ACR will inform the FDA of your accreditation, and you will receive your FDA certificate or interim notice. An interim notice will allow you to begin performing mammography until a permanent FDA certificate arrives. MQSA applies only to screening and diagnostic mammography machines.

State Certification is machine-based and results in individual certificates for each machine used to perform mammography. This includes biopsy and stereotactic units *in addition to* screening and diagnostic units. State certificates are issued only by the California DHS. Please allow 3 - 5 days for application processing.

The following guidelines should help you in clarifying the complicated process of satisfying both State and Federal requirements. In addition, please note that there is important information on the last page of this document regarding inspections, clinical image review, and changes in the way your state certificates are now being renewed.

If you need additional information, contact the State of California for state certification questions, and/or your accrediting body for federal certification questions.

New Facility - *After receiving state certificates and interim notice, you may perform patient exams.*

State

1. Notify the DHS, Radiologic Health Branch (RHB) of your intention to perform mammography.

2. Have an authorized medical physicist perform a complete evaluation of facility and machine(s). Deficiencies found must be corrected.

3. Fax or mail application for State certificates, physicist report(s), including corrective action documentation of deficiencies, and machine registration forms to the RHB.

4. Have onsite inspection by California inspector.

5. When inspection and all submissions are approved, you will receive a State certificate for each approved machine valid for up to six months, the time allotted for clinical image review (CIR).

6. After passing CIR, send/fax the RHB the ACR certificate for each machine. You will receive a new State certificate for each machine issued a ACR certificate, valid until the FDA certificate expiration date.

Federal

1. Contact the ACR to be your AB.

2. Complete the ACR application and submit it along with requested attachments to the ACR.

3. ACR will inform FDA to send you an interim notice. A provisional certificate will be issued from the FDA for a period of six months.

4. The ACR will send you labels to complete the CIR portion of the accreditation process. CIR results **must** be received before your certificates expire.

5. If you pass CIR you will become "fully accredited". The ACR will inform FDA of your accreditation, and your facility will receive a new FDA certificate valid for up to three years.

6. You must begin the renewal process approximately 9 months prior to your expiration date. If you have not been notified by ACR, call them to request an application and labels for CIR.

Accredited Facility Adding New Machine – Only after you receive a state certificate for the new machine can you begin performing patient exams with new machine.

State

1. Notify the RHB that you will be purchasing a new machine.

2. Have an authorized medical physicist perform complete evaluation of new machine. Deficiencies found by the physicist must be corrected.

3. Fax or mail physicist report, including corrective action documentation of deficiencies; application, and machine registration forms (transfer notice if moved form another facility) to the RHB.

4. No onsite inspection is required, however your machine registration fee status will be reviewed. If you are past due, the DHS will not issue a State certificate until all fees are paid.

Federal

1. Notify ACR that you have a new machine.

2. ACR will send CIR labels.

3. When you pass CIR, this new machine will be accredited under your existing FDA certificate.

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State

Federal

5. When all submittals are approved, and after verification that your fees are current, you will receive a State certificate for the new machine valid for up to six months, the time allotted for CIR.

6. After passing CIR, send/fax the RHB the ACR certificate for the new machine. You will receive a new State certificate, valid until the FDA certificate expiration date.

Federal and State Certificate Renewal - You may continue performing mammography until federal and State certificates expire.

State

1. Your State certificate(s) will expire on the same day as your FDA certificate. To renew your State certificate(s), you must: complete the renewal CIR with the ACR; mail/fax the most current physicist report(s) (including documentation of correcting deficiencies), State application, and ACR certificates to the RHB; have had satisfactory annual inspections by the State of California; and be current with all California registration fees.

2. When all submittals are approved and after verification that your fees are current, you will receive a new State certificate for each machine issued a ACR certificate, valid until the FDA certificate expiration date.

Federal

1. If you have not been contacted by the ACR at least 9 months prior to your FDA certificate expiration date, call them and ask for a renewal application.

2. Submit completed ACR application and required attachments to the ACR.

3. Submit images as directed by the ACR.

4. When your machines pass CIR, the ACR will inform the FDA of your successful renewal of accreditation and your facility will receive a new FDA certificate valid for up to three years.

Mammography Facility Closes or Merges with Other Facility

State

1. Notify the RHB if you will be terminating your mammographic services.

2. Send a letter informing the RHB where all patient mammography records and mammograms will be maintained and information about how patients may obtain their records.

3. After any X-ray machines, including mammography machines, have been transferred to a third party or disabled, send to the RHB machine registration forms showing deletion of X-ray equipment. Include a transfer notice for any machine that is moved to another active facility.

4. Return all state certificates to the RHB.

Federal

1. Notify ACR in writing that you wish to withdraw from the MQSA program.

2. ACR will notify FDA of your request.

3. If merging, tell ACR that you are adding machines to the combined facility, and terminating another facility.

More information:

-Inspections- Both Federal law and State law mandate inspections. The State of California has a contract with the FDA to perform MQSA inspections within the state. State inspectors have been specifically trained by the FDA to be proficient in MQSA inspections. Your mammography program will be inspected once per year. One inspector will perform both the state and federal inspections at the same time.

-Clinical Image Review Reminders- Your CIR films must be submitted by the deadline given to you by the ACR. Be aware that the CIR process takes 8 - 10 weeks to complete after you mail the films. If your State certificate expires and you have not completed the CIR process, you will have to cease performing mammography as of the expiration date. Please notify the ACR and the RHB prior to your expiration date for further instructions.

-Monitor The Expiration Date On Your State Certificates - *State certificates are tied to your federal accreditation renewal and facilities are responsible for renewal of their own State certificates*. If any of your State certificates have expired, notify the RHB immediately. Performing mammography with expired State certificates is illegal!

If you have any further questions about this material, you may reach the California Radiologic Health Branch at (916) 440-7898, fax (916) 440-7999.
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